APR 21 2004 P.

PATENT

Attorney Docket No.: DERM1100-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Rheins and Morhenn

Art Unit: 1647

Application No.:

09/375,609

Examiner: L.Spector

Filed:

August 17, 1999

Title:

METHODS AND KITS FOR OBTAINING AND ANALYZING SKIN

SAMPLES FOR THE DETECTION OF NUCLEIC ACIDS (As Amended)

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and copies are enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and that its consideration be made of written record in the application file.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on April 23 2004, in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Karen LePari

In re Application of:

Rheins and Morhenn

Application No.: 09/375,609

Filing Date: August 17, 1999

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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement as each item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated June 26, 2003, which is not more than three months prior to the filing of this statement.

However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1355. A duplicate copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

PATENT

Atty Docket No.: DERM1100-1

Date: April 23, 2004

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| FORM PTO-1449 | Docket No.: | Serial No.: | |
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| U.S. Department of Commerce Patent and | DERM1100-1 | 09/375,609 | |
| Trademark Office / | | | |
| APR 2 7 2004 | Applicants: Rheins and Morhenn | | |
| INFORMATION DISCEQUEE STATEMENT | Filing Date: | Group Art Unit: | |
| BY APPLICANT | August 17, 1999 | 1647 | |
| OAL CALL | | | |

U.S. PATENT DOCUMENTS

| EXAM. INITIALS | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB- CLASS | FILING DATE |
|-------------------|--------------------|------|------|-------|---------------|----------------|
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FOREIGN PATENT DOCUMENTS

| EXAM. INITIALS | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION (YES/NO) |
|-------------------|--------------------|------|---------|-------|---------------|-------------------------|
| | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

| AP | Bunge, A. and Guy, R., "Improvement of Methodology for Assessing Bioequivalence of Topical Products," http://www.fda.gov/ohrms/dockets/ac/03/slides/3996S2 07 Bunge.pdf. |
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| AQ | "Draft Guidance for Industry on Topical Dermatological Drug Product NDA's and ANDA's-In Vivo Bioavailability, Bioequivalence, in Vitro Release and Associated Studies: Dermatopharmacokineticds (DPK) Method Issues", http://srpub.phrma.org/letters/08.17.98.topical.derm.html . PRMA 1998 |
| AR | "Washington Report: Skin Tape Stripping Method for Generic Dermatologic Drug Approval Remains in Question", http://www.aadassociation.org/old/washReports/dec99_washrep.html . (1996). |
| | |

| EXAMINER | DATE CONSIDERED |
|----------|-----------------|
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449